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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,938	06/25/2001	Graham P. Allaway	50875-DA/JPW/SHS	9272

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EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,938	ALLAWAY ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51 and 53-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51 and 53-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.

2. This Office Action is in response to the amendment received on March 10, 2006. Claim 52 is cancelled. Claims 51 and 53-57 are amended. Claims 51 and 53-58 are pending and are under consideration in this Office action.

3. The rejection of claims 51 and 53-58 under the nonstatutory double patenting over claims 15 and 16 of US 09/412,284 now US patent 6,972, 126 **is withdrawn** in view of approval of terminal disclaimer.

4. The rejection of claims 51 and 53-58 under the nonstatutory double patenting over claims 15 and 16 of Application No. 09/852,238 **is withdrawn** in view of the abandonment of 09/852,238.

5. The rejection of claims 51 and 53-58 under the nonstatutory double patenting over claims 1-5, 18 and 31 of Application No. 10/371,483 **is maintained**. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. The rejection of claims 51 and 53-58 under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, **is withdrawn** in view of the amendment.

7. The rejection of claims 51 and 53-58 under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement **is withdrawn** in view of the amendment and Applicant's argument.

8. The rejection of claims 51, 53-58 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement **is maintained.**

9. Applicant arguers that the specification has sufficient written description about the claimed antibodies against CCR5 because (1) the specification clearly discloses an isolated antibody which, is prepared against a human CCR5 chemokine receptor on the surface of a CD4+ cell and inhibits HIV-1 infection of such CD4+ cell, as recited in independent claim 51 (see, inter alia, page 11, lines 32-34; page 12, lines 10-12; page 22, lines 27-30); (2) the complete nucleotide and amino acid sequence of the CCR5 gene and receptor, respectively, were in the public domain prior to the effective filing date of the subject application (see Samson et al. [1996]); (3) the specification discloses (a) the identification of the human CCR5 receptor as the chemokine receptor that mediates fusion of CD4+ cells to primary HIV-1 strains (see, inter alia, page 31, lines 8-11, and page 35, line 19 to page 36, line 16), (b) the cloning of the human CCR5 receptor (page 33, lines 3-17, and page 34, lines 23-26) , and (c) the expression of functional human CCR5 ire human CD4-expressing cell lines (page 34, lines 27-30); (4) one skilled in the art would understand that disclosing the sequence of the human CCR5 receptor and expressing

this receptor on the surface of a CD4+ cell effectively describes antibodies that bind the receptor on the surface of the cell since such antibodies are readily generated by routine experiments (see page 12, lines 12-13, and page 22, lines 27-30); and (5) the specification describes a routine RET assay for screening antibodies prepared against the human CCR5 receptor on the surface of the cell for their ability to inhibit fusion of H1V-1 to CD4+ cells, thereby inhibiting HIV-1 infection of CD4+ cells (see, inter alia, page 17, line 33 to page 18, line 15, and page 4, lines 8-13).

10. Applicant's arguments are considered but found not persuasive. Just because CCR5 was known to mediate HIV-1 entry, its sequence was in the public domain prior to the effective filling date of the instant application, and a person skilled in the art has knowledge how to make an antibody in general does not mean the Applicant was in possession of an antibody against CCR5. The instant specification only disclosed a basic functional characteristic of CCR5 antibodies, which is bind to CCR5 (see specification, page 11, lines 32-34; page 12, lines 10-12; page 22, lines 27-30), but does not disclose any specific sequences or partial structures of the antibodies, or physical and/or chemical properties of the antibodies against CCR5. The MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that

> "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

11. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for a genus of CCR5 antibodies and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of an antibody against CCR5 as claimed.

12. Following are new grounds of rejections:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 51 and 53-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 98 and 100-104 and 118-134 of copending Application No. 09/594,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a same product.

14. The instant claims 51 and 53-58 are drawn to an isolated antibody that binds to CCR5 chemokine receptor on the surface of a CD4 cell and inhibits HIV-1 infection of such CD4 cell, wherein the antibody is a monoclonal antibody.

15. Claims 98,100-104 and 118-134 of copending Application No. 09/594,983 are drawn to a monoclonal antibody designated PA14, which binds to an epitope of CCR5 present on the surface of a cell expressing CCR5.

16. The claim limitation of instant application 09/888,938 clearly covers a genus of antibodies against CCR5, while claims 98,100-104 and 118-134 of copending Application No. 09/594,983 are directed to a species of monoclonal antibody PA14 against CCR5. According to MPEP, a species will anticipate a claim to a genus. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (Gosteli claimed a genus of 21 specific chemical species of bicyclic thia-aza compounds in Markush claims. The prior art reference applied against the claims disclosed two of the chemical species. The parties agreed that the prior art species would anticipate the claims unless applicant was entitled to his foreign priority date) (see MPEP 2131.02). In the instant case, the monoclonal antibody PA14 of copending application 09/594,983 (species) anticipates an antibody against CCR5 (genus) of instant claims 51 and 53-58.

17. Claims 51 and 56-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 99-108 of copending Application No. 10/763,454. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a same product.

18. Claims 99-108 of copending application 10/763,545 are directed a composition which

comprises a monoclonal antibody, wherein the monoclonal antibody binds to an epitope of CCR5, wherein the antibody is selected from the group consisting of antibodies PA8, PA9, PA10, PA11, PA12 and PA14.

19. As discussed *supra*, the CCR5 antibodies PA8, PA9, PA10, PA11, PA12 and PA14 (species) anticipate an antibody against CCR5 (genus), thus, claims 99-108 of copending application 10/763,545 anticipate the instant claims 51 and 56-58.

Remarks

20. No claims are allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The Examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Bo Peng, Ph.D.

June 8, 2006

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